(4) Methods used in or the facilities and controls used for the manufacture, processing, or packing of the product from such methods, facilities, and controls described in the application;

(5) Labeling from the specimens contained in the application; or

(b) The unexplained omission in whole or in part from an application or from an amendment or supplement to an application or from any record or report required under the provisions of section 512 of the act and § 510.300 or § 510.301 of this chapter of any information obtained from:

(1) Investigations as to the safety, effectiveness, identity, strength, quality, or purity of the drug, made by the applicant on the drug, or

(2) Investigations or experience with the product that is the subject of the application, or any related product, available to the applicant from any source if such information is pertinent to an evaluation of the safety, effectiveness, identity, strength, quality, or purity of the drug, when such omission would bias an evaluation of the safety or effectiveness of the product.

(c) Any nonclinical laboratory study contained in the application was not conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, and the application fails to include a brief statement of the reason for the noncompliance.

[40 FR 13825, Mar. 27, 1975, as amended at 49 FR 7226, Feb. 28, 1984; 50 FR 7517, Feb. 22, 1985]

Subpart B—Administrative Actions on Applications

§ 514.100 Evaluation and comment on applications.

(a) After the filed application has been evaluated, the applicant will be furnished written comment on any apparent deficiencies in the application.

(b) When the description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such new animal drug appears adequate on its face, but it is not feasible to reach a conclusion as to the safety and effectiveness of the new animal drug solely from consideration of this description, the applicant may be notified that an establishment inspection is required to verify their adequacy.

(c) A request for samples of a new animal drug or any edible tissues and byproducts of animals treated with such a drug, shall specify the quantity deemed adequate to permit tests of analytical methods to determine their adequacy for regulatory purposes. The request should be made as early in the 180-day period as possible to assure timely completion. The date used for computing the 180-day limit for the purposes of section 512(c) of the act shall be moved forward 1 day for each day after the mailing date of the request until all of the requested samples are received. If the samples are not received within 90 days after the request, the application will be considered withdrawn without prejudice.

(d) The information contained in an application may be insufficient to determine whether a new animal drug is safe or effective in use if it fails to include (among other things) a statement showing whether such drug is to be limited to prescription sale and exempt under section 502(f) of the act from the requirement that its labeling bear adequate directions for lay use. If such drug is to be exempt, the information may also be insufficient if:

(1) The specimen labeling proposed fails to bear adequate information for professional use including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer such drug can use the drug for the purposes for which it is intended, including all purposes for which it is to be advertised, or represented, in accordance with § 201.105 of this chapter, and information concerning hazards, contraindications, side effects, and precautions relevant with respect to any uses for which such drug is to be prescribed.

(2) The application fails to show that the labeling and advertising of such drug will offer the drug for use only under those conditions for which it is offered in the labeling that is part of the application.

(3) The application fails to show that all labeling that furnishes or purports to furnish information for professional use of such drug will contain, in the same language and emphasis, the information for use including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant warnings, hazards, contraindications, side effects, and precautions, which is contained in the labeling that is part of the application in accordance with § 201.105 of this chapter.

(e) The information contained in an application will be considered insufficient to determine whether a new animal drug is safe and effective for use when there is a refusal or failure upon written notice to furnish inspectors authorized by the Food and Drug Administration an adequate opportunity to inspect the facilities, controls, and records pertinent to the application.

(f) On the basis of preliminary consideration of an application or supplemental application containing typewritten or other draft labeling in lieu of final printed labeling, an applicant may be informed that such application is approvable when satisfactory final printed labeling identical in content to such draft copy is submitted.

(g) When an application has been found incomplete on the basis of a need for the kind of information described in § 514.6, such application shall be considered withdrawn without prejudice to future filing on the date of issuance of the letter citing the inadequacies contained in the application, unless within 30 days the sponsor chooses to avail himself of the opportunity for hearing as prescribed by § 514.111.

§ 514.105 Approval of applications.

(a) The Commissioner shall forward for publication in the FEDERAL REGISTER a regulation prescribing the conditions under which the new animal drug may be used, including the name and address of the applicant; the conditions and indications for use covered by the application; any tolerance, withdrawal period, or other use restrictions; any tolerance required for the new animal drug substance or its metabolites in edible products of food-producing animals; and, if such new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements) applicable to any animal feed; and such other information the Commissioner deems necessary to assure safe and effective use.

(b) He shall notify the applicant by sending him a copy of the proposed publication as described in paragraph (a)(1) of this section.

[40 FR 13825, Mar. 27, 1975, as amended at 51 FR 7392, Mar. 3, 1986; 64 FR 63203, Nov. 19, 1999]

§ 514.106 Approval of supplemental applications.

(a) Within 180 days after a supplement to an approved application is filed pursuant to § 514.8, the Commissioner shall approve the supplemental application in accordance with procedures set forth in § 514.105(a)(1) and (2) if he/she determines that the application satisfies the requirements of applicable statutory provisions and regulations.

(b) The Commissioner will assign a supplemental application to its proper category to ensure processing of the application.

(1) *Category I.* Supplements that ordinarily do not require a reevaluation of any of the safety or effectiveness data in the parent application. Category I supplements include the following:

(i) A corporate change that alters the identity or address of the sponsor of the new animal drug application (NADA).

(ii) The sale, purchase, or construction of manufacturing facilities.

(iii) The sale or purchase of an NADA.

(iv) A change in container, container style, shape, size, or components.

(v) A change in approved labeling (color, style, format, addition, deletion, or revision of certain statements, e.g., trade name, storage, expiration dates, etc).

(vi) A change in promotional material for a prescription drug not exempted by § 514.8(a)(3)(i) and (a)(3)(ii).

(vii) Changes in manufacturing processes that do not alter the method of manufacture or change the final dosage form.